

Guidance for using the BinaxNOW™ COVID-19 Ag Card

November 12, 2020

What is the BinaxNOW™ COVID-19 Ag Card?

The Abbott BinaxNOW™ COVID-19 Ag Card is a rapid antigen test in a card format that detects SARS-CoV-2 protein antigens present in a nasal swab specimen. This is a diagnostic test designed for use in individuals suspected of having COVID-19 by their healthcare provider within the first 7 days of symptom onset. Testing is done at the point of care, and results are available in 15 minutes. Results are read visually, and no instrumentation is required. The test must be conducted within one hour of swab collection; the swabs must remain dry and are not stored in viral transport media. The test is authorized for use under a U.S. Food and Drug Administration (FDA) Emergency Use Authorization (EUA).

Additional information about the test:

EUA, <https://www.fda.gov/media/141567/download>

Fact Sheet for Healthcare Providers, <https://www.fda.gov/media/141568/download>

Fact Sheet for Patients, <https://www.fda.gov/media/141569/download>

FDA IN Vitro Diagnostics EUAs, <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas>

Who can conduct the BinaxNOW™ COVID-19 Ag Card test?

This test is authorized for use in Clinical Laboratory Improvement Amendments (CLIA)-certified laboratories and as a point-of-care test in patient care settings such as doctor's offices and other facilities operating under a CLIA Certificate of Waiver. A Certificate of Waiver can be obtained through the Idaho Bureau of Laboratories (IBL). Facilities must complete the federal form CMS-116 (link provided below). The CLIA form may be mailed to Lab Improvement, 2220 Old Penitentiary Road, Boise, Idaho 83712, emailed to LabImprovement@dhw.idaho.gov, or faxed to the IBL office at (208) 334-4067. The fee is \$180* and the certificate is renewable every two years.

Facilities that are not considered traditional patient care settings, such as schools and shelters for people experiencing homelessness, can perform the BinaxNOW™ COVID-19 Ag Card tests, but they **must** obtain a CLIA Certificate of Waiver and comply with other requirements including obtaining consent, protecting patient privacy, using appropriate infection prevention measures, and reporting results to public health. In addition, note that all components of the BinaxNOW™ test kit should be discarded as biohazard waste.

The BinaxNOW™ COVID-19 Ag Card is a prescription-only test and must be ordered by a provider or other authorized person. A standing order can be used. For assistance identifying an appropriate ordering provider, please contact your local Public Health District (see link below).

Additional information:

Idaho Bureau of Laboratories CLIA information, <https://healthandwelfare.idaho.gov/providers/idaho-laboratories-and-testing/clinical-lab-certification>

CLIA Information FAQ:

<https://publicdocuments.dhw.idaho.gov/WebLink/DocView.aspx?id=3420&dbid=0&repo=PUBLIC-DOCUMENTS&cr=1>

Form CMS-116, <https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS116.pdf>

Idaho's Public Health Districts: <http://healthandwelfare.idaho.gov/health-wellness/community-health/public-health-districts>

* An invoice will be sent following application receipt. Reimbursement may be available for schools; please contact your local Public Health District.

Do results of BinaxNOW™ COVID-19 Ag Card tests have to be reported to public health, and who reports them?

Results of all positive and negative BinaxNOW™ COVID-19 Ag Card tests must be reported to public health authorities within 24 hours of test completion by the laboratory or the entity performing the test.* The following information must be reported:

- About the person tested: Name, Date of Birth, Sex, Address, Phone Number, Symptom Onset Date, Race, Ethnicity
- About the test performed: Specimen collection date, Accession number, Specimen Source, Type of test performed (PCR, Antigen), Date test performed, Result, Ordering provider name, phone number, and address, Performing facility name, phone number, and address.

Contact the Idaho Division of Public Health, Bureau of Communicable Disease Prevention Epidemiology Section at Epimail@dhw.idaho.gov to begin the electronic reporting onboarding process.

In addition, any suspected occurrence of a false positive or false negative result must be reported to the FDA and the manufacturer. See the EUA (link below) for details.

Additional information:

Reporting guidance for COVID-19, <https://www.hhs.gov/sites/default/files/covid-19-laboratory-data-reporting-guidance.pdf>

EUA, <https://www.fda.gov/media/141567/download>

*CMS-certified long-term care facilities are required to submit testing data to CDC's National Healthcare Safety Network (NHSN) and should refer to the HHS guidance (link provided above) for details.

What training is available for performing the BinaxNOW™ COVID-19 Ag Card test?

Training is required prior to running the test. Training videos detailing the step-by-step process of running the test can be found on the Abbott website (link below) and should be watched in their entirety before performing tests on individuals. Any facility performing BinaxNOW™ COVID-19 Ag Card tests must also be familiar with infection control precautions and use appropriate personal protective equipment.

Training resources:

Training on how to set up and use the BinaxNOW™ COVID-19 Ag Card,

<https://www.globalpointofcare.abbott/en/support/product-installation-training/navica-brand/navica-binaxnow-ag-training.html>

Instructions for Use, <https://www.fda.gov/media/141570/download>

Additional Information:

Centers for Disease Control and Prevention (CDC) Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID 19),

<https://www.cdc.gov/coronavirus/2019-ncov/lab/lab-biosafety-guidelines.html>

CDC Interim Guidelines for Collection, Handling, and Testing Clinical Specimens for COVID-19,

<https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html>

When should the BinaxNOW™ COVID-19 Ag Card test be used?

(See also tables starting on page 4.)

This test is best used for individuals with COVID-19-like symptoms who are suspected of having COVID-19 by their healthcare provider and seek medical care within the first 7 days of illness onset. Reverse transcriptase polymerase chain reaction (RT-PCR) tests are still considered the gold standard for diagnosing COVID-19. However, this BinaxNOW™ test may be useful in certain situations where RT-PCR tests are not immediately available or have a prolonged (>48 hour) turnaround time, such as rural settings with limited access to testing and a known high prevalence of COVID-19. They may also be useful in settings where multiple people have COVID-19-like symptoms and need to be tested with a rapid turn-around time (e.g. symptomatic staff and/or residents in group settings like long term care facilities, workplaces, schools, and correctional facilities). However, results must be interpreted with caution, as discussed further below.

These BinaxNOW™ tests are generally not recommended for screening or testing asymptomatic individuals. Rapid antigen tests like BinaxNOW™ are less sensitive than the RT-PCR test, which means that false negative results might occur when viral loads are low, particularly very early or very late in the course of infection. Furthermore, data to guide the use of rapid antigen tests as a screening test in asymptomatic individuals are limited.

Additional guidance from the Idaho Department of Health & Welfare: <https://coronavirus.idaho.gov/wp-content/uploads/2020/09/Rapid-Antigen-Test-Recommendations-V2-FINAL.pdf>

How should BinaxNOW™ COVID-19 Ag Card test results be interpreted, and what are the next steps?

See tables below for examples of use in:

1. Symptomatic persons in non-congregate settings
2. Symptomatic persons in congregate settings
3. Asymptomatic persons

1. SYMPTOMATIC PERSONS IN NON-CONGREGATE SETTINGS (including college/university students in dorms)			
Individual being tested	Result ¹	Interpretation	Next steps
Symptomatic individual suspected of COVID-19 by a healthcare provider, within 7 days of symptom onset (i.e., high pre-test probability, lower-risk setting)	Positive	COVID-19 diagnosis	No confirmatory testing needed. Isolate for at least 10 days after symptom onset. ^{2,3}
	Negative	Result considered a “presumptive negative” and should not be used as the sole criteria to discontinue isolation or transmission-based precautions	Confirm with RT-PCR testing. Isolate until results of RT-PCR are received or at least 10 days after symptom onset. ^{2,3}
Symptomatic individual with mild, nonspecific symptoms (e.g., runny nose or sore throat) and no known exposure to SARS-CoV-2 (i.e., low pre-test probability, lower-risk setting)	Positive	Presumptive positive	Confirm with RT-PCR testing. ⁴ Isolate until result of second test is known.
	Negative	Negative	Recommend usual public health risk mitigation strategies (i.e., physical distancing, mask wearing, and regular hand hygiene).
Symptomatic individual suspected of COVID-19 by a healthcare provider, more than 7 days from symptom onset (not a recommended use of the BinaxNOW COVID-19 Ag Card test) (i.e., high pre-test probability but outside optimal testing window, lower-risk setting)	Positive	COVID-19 diagnosis	No confirmatory testing needed. Isolate for at least 10 days after symptom onset. ^{2,3}
	Negative	Result considered a “presumptive negative” and should not be used as the sole criteria to discontinue isolation or transmission-based precautions	Isolate for at least 10 days after symptom onset. ^{2,3} Confirmatory RT-PCR testing can be considered if needed for patient management or infection control reasons (e.g., identifying and isolating close contacts).

2. SYMPTOMATIC PERSONS IN CONGREGATE SETTINGS

Individual being tested	Result ¹	Interpretation	Next steps
Symptomatic individual in a congregate living facility with a widespread outbreak who has had a known exposure, within 7 days of symptom onset (i.e., high pre-test probability, high-risk setting)	Positive	COVID-19 diagnosis	No confirmatory testing needed. Isolate for at least 10 days after symptom onset. ^{2,3}
	Negative	Result considered a “presumptive negative” and should not be used as the sole criteria to discontinue transmission-based precautions	Confirm with RT-PCR testing. Isolate individual until results of RT-PCR are received or for at least 10 days after symptom onset. ^{2,3}
Symptomatic individual, entering a congregate setting (such as a homeless shelter or jail), with mild, nonspecific symptoms (e.g., sore throat) and no known exposure to SARS-CoV-2 (i.e., low pre-test probability, high-risk setting)	Positive	Presumptive positive	Confirm with RT-PCR testing. ⁴ Isolate until result of second test is known.
	Negative	Presumptive negative	Confirm with RT-PCR testing. Isolate until results of RT-PCR are received or for at least 10 days after symptom onset. ^{2,3}
Symptomatic individual in a congregate living facility with a widespread outbreak who has had a known exposure, more than 7 days from symptom onset (not a recommended use of the BinaxNOW COVID-19 Ag Card test) (i.e., high pre-test probability but outside optimal testing window, high-risk setting)	Positive	COVID-19 diagnosis	No confirmatory testing needed. Isolate for at least 10 days after symptom onset. ^{2,3}
	Negative	Result considered a “presumptive negative” and should not be used as the sole criteria to discontinue transmission-based precautions	Confirm with RT-PCR testing. Isolate until results of RT-PCR are received or for at least 10 days after symptom onset. ^{2,3}

3. ASYMPTOMATIC PERSONS (not a generally recommended use of BinaxNOW COVID-19 Ag Card tests)

Individual being tested	Result ¹	Interpretation	Next steps
Asymptomatic individual identified as a close contact of someone with COVID-19, not residing in a congregate living facility (i.e., medium pre-test probability, lower-risk setting)	Positive	Person considered SARS-CoV-2 positive	No confirmatory testing needed. Isolate for at least 10 days from date of test. ^{2,3}
	Negative	Result considered a “presumptive negative” and should not be used as the criteria to discontinue isolation	Continue self-isolation for 14 days from exposure and self-monitor for symptoms; re-test if symptoms develop.
Asymptomatic individual with no known exposure, such as screening teachers (i.e., low pre-test probability, lower-risk setting)	Positive	Presumptive positive	Confirm with RT-PCR testing. ⁴ Isolate until result of second test is known.
	Negative	Negative	Recommend usual public health risk mitigation strategies (i.e., physical distancing, mask wearing, and regular hand hygiene).

¹ Invalid tests should be repeated. A positive result does not rule out other pathogens; coinfections can occur.

² Interim Guidance for Isolation https://coronavirus.idaho.gov/wp-content/uploads/2020/07/Interim-Guidance-for-Isolation-for-COVID-19_19july2020.pdf

³ Some individuals who are immunocompromised may require a longer duration of isolation. See [Discontinuation of Transmission-Based Precautions and Disposition of Patients with COVID-19 in Healthcare Settings \(Interim Guidance\) | CDC](#) for additional information.

⁴ If RT-PCR testing is not readily available or if there is a prolonged turnaround time for results (e.g., >48 hours), an alternative to confirmatory testing with RT-PCR is to immediately repeat the BinaxNOW COVID-19 Ag Card test. If the second BinaxNOW COVID-19 Ag Card test is negative, the person is considered not infected.

Additional considerations for high priority settings

K-12 school system

Can BinaxNOW™ COVID-19 Ag Card tests be used to test symptomatic individuals who have known or possible exposure to someone with COVID-19?

Yes. The BinaxNOW™ COVID-19 Ag Card test is authorized for use in individuals suspected of COVID-19 by their healthcare provider within the first seven days of symptom onset. Testing a student, teacher, or staff member with COVID-19 symptoms who has had a known or possible exposure to COVID-19 is an appropriate use of this BinaxNOW™ test. A positive result should be interpreted as a **true positive**, and further confirmatory testing with RT-PCR is not necessary. A negative result should be interpreted as a **presumptive negative**; confirmatory RT-PCR testing is recommended, and the individual should self-isolate until results of the RT-PCR test are known.

Can BinaxNOW™ COVID-19 Ag Card tests be used to test all students in a classroom or on a sports team with known or possible exposure to someone with COVID-19 (e.g., another classmate or team member has been diagnosed with COVID-19)?

No. The BinaxNOW™ COVID-19 Ag Card test is only authorized for use in symptomatic individuals. Any student who is identified as a close contact (a person who was within 6 feet for at least 15 minutes of someone who is infected) should self-isolate at home for at least 14 days after the last contact with the COVID-19-positive individual. If the exposed student develops symptoms, testing can be performed with a BinaxNOW™ COVID-19 Ag Card test. A positive result should be interpreted as a **true positive**, and further confirmatory testing with RT-PCR is not necessary. A negative result should be interpreted as a **presumptive negative**; confirmatory RT-PCR testing is recommended.

Can BinaxNOW™ COVID-19 Ag Card tests be used for return-to-school considerations after a known or possible exposure?

No. Any individual identified as a close contact (a person who was within 6 feet for at least 15 minutes of someone who is infected) should self-isolate at home for at least 14 days after the last contact with the COVID-19-positive individual. Testing can be pursued at 5–7 days after last contact with the COVID-19-positive individual or if symptoms develop. However, the exposed individual must complete 14 days of self-isolation before returning to school even if the test is negative.

Congregate living facilities other than long-term care facilities (e.g., correctional facilities, state hospitals, homeless shelters, etc.)

Can BinaxNOW™ COVID-19 Ag Card tests be used to test asymptomatic individuals on entrance to the facility?

No. The BinaxNOW™ COVID-19 Ag Card test is only authorized for use in symptomatic individuals. Screening testing of asymptomatic individuals should be conducted with RT-PCR tests, and appropriate infection prevention measures should be undertaken until results are known.

Although it is not recommended that the BinaxNOW™ COVID-19 Ag Card test be used to test asymptomatic individuals, if the tests are used in this setting, it is extremely important to interpret results cautiously as there are few data to indicate how this test will perform in this clinical context; there is a risk of both false positive and false negative results. Specifically:

- An asymptomatic individual who tests **positive** on the BinaxNOW™ COVID-19 Ag Card test upon entrance to a facility **should not be cohorted** with other COVID-19-positive individuals. Rather, the individual should be isolated from others, and a confirmatory RT-PCR test should be performed immediately. Further actions should be based on the RT-PCR test result.
- An asymptomatic individual who tests **negative** on the BinaxNOW™ COVID-19 Ag Card test upon entrance to a facility **should not be cohorted** with other COVID-19-negative individuals. Rather, the individual should be cared for following the facility's usual infection prevention measures for new entrants to the facility (which may include isolation from others until 14 days after the last contact with anyone who might have had COVID-19).

Can BinaxNOW™ COVID-19 Ag Card tests be used to test a symptomatic individual on entrance to the facility, or an individual residing in the facility who develops COVID-19-like symptoms?

Yes. The BinaxNOW™ COVID-19 Ag Card test is authorized for use in individuals suspected of COVID-19 by their healthcare provider within the first seven days of symptom onset. A positive result should be interpreted as a **true positive**, and further confirmatory testing with RT-PCR is not necessary. A negative result should be interpreted as a **presumptive negative**; confirmatory RT-PCR testing is recommended, and the individual should be isolated until results of the RT-PCR test are known.

Can BinaxNOW™ COVID-19 Ag Card tests be used to test everyone on a unit that has a COVID-19 outbreak?

No. The BinaxNOW™ COVID-19 Ag Card test is only authorized for use in symptomatic individuals. Outbreak testing of asymptomatic individuals should be done with RT-PCR tests. Appropriate infection prevention measures should be undertaken until outbreak testing is completed.

Healthcare facilities with limited access to RT-PCR testing (such as a rural or economically disadvantaged setting or an after-hours clinic), including testing of healthcare workers

Can BinaxNOW tests be used to test a symptomatic individual who has a known or possible exposure to someone with COVID-19?

Yes. The BinaxNOW™ COVID-19 Ag Card test is authorized for use in individuals suspected of having COVID-19 by their healthcare provider within the first seven days of symptom onset. Testing an individual with COVID-19 symptoms who has had a known or possible exposure to COVID-19 is an appropriate use of this BinaxNOW™ test. A positive result should be interpreted as a **true positive**, and further confirmatory testing with RT-PCR is not necessary. A negative result should be interpreted as a **presumptive negative**; confirmatory RT-PCR testing is recommended, and the individual should self-isolate until results of the RT-PCR test are known.

Can BinaxNOW tests be used to test an asymptomatic individual who is a close contact of someone with COVID-19?

Not a recommended use of BinaxNOW™ COVID-19 Ag Card test. The BinaxNOW™ COVID-19 Ag Card test is only authorized for use in symptomatic individuals. Any individual who is identified as a close contact (a person who was within 6 feet for at least 15 minutes of someone who is infected) should self-isolate at home for at least 14 days after the last contact with the COVID-19-positive individual. If the exposed individual develops symptoms, testing can be performed with a BinaxNOW™ COVID-19 Ag Card test. A positive result should be interpreted as a **true positive**, and further confirmatory testing with RT-PCR is not necessary. A negative result should be interpreted as a **presumptive negative**; confirmatory RT-PCR testing is recommended.

Although not generally recommended, if the BinaxNOW™ COVID-19 Ag Card test is used to test an asymptomatic individual identified as a close contact of someone with COVID-19, see Table 3, above, for interpretation of results.

Colleges and university students

Can BinaxNOW™ COVID-19 Ag Card tests be used as part of a screening testing strategy for COVID-19 (e.g., to screen students upon arrival to the campus after a break)?

No. The BinaxNOW™ Ag Card test is only authorized for use in symptomatic individuals. Screening testing of asymptomatic individuals should be done with RT-PCR tests.

Can BinaxNOW™ COVID-19 Ag Card test be used in a student health clinic to test individuals with symptoms suggestive of COVID-19?

Yes. The BinaxNOW™ COVID-19 Ag Card test is authorized for use in individuals suspected of having COVID-19 by their healthcare provider within the first seven days of symptom onset. A positive result in a symptomatic individual should be interpreted as a **true positive**, and further confirmatory testing with RT-PCR is not necessary. A negative result should be interpreted as a **presumptive negative**; confirmatory RT-PCR testing is recommended, and the individual should be isolated until results of the RT-PCR test are known.

Long-term care facilities

Long-term care facilities using the BinaxNOW™ COVID-19 Ag Card test should refer to the Centers for Disease Control and Prevention's (CDC's) [Considerations for Use of SARS-CoV-2 Antigen Testing in Nursing Homes](#) and to the Idaho guidance "[Use of Rapid Antigen Tests in Idaho Long-term Care Facilities](#)."

What is the difference between BinaxNOW, the Abbot ID NOW, and high-throughput RT-PCR tests for SARS-CoV-2?

Test	Type of test	Instrumentation	Specimen type	Testing time frame	Time to results	Recommended uses
BinaxNOW™ COVID-19 Ag Card (Abbott)	Rapid antigen	None	nasal swab (included in test kit)	Within 1 hour of collection	15 minutes	Symptomatic individuals within the first seven days of the onset of symptoms
ID NOW™ (Abbott)	Nucleic acid amplification test	ID NOW™ instrument	nasal, nasopharyngeal or throat swabs	Within 1 hour of collection	13 minutes or less	Symptomatic individuals within the first seven days of the onset of symptoms
RT-PCR (multiple suppliers)	Nucleic acid amplification test	Real-time PCR machine	nasal, nasopharyngeal or throat swabs; other sample types	Can be refrigerated or frozen and tested later	Variable	Symptomatic individuals, asymptomatic individuals identified as close contacts to a COVID-19 case, and for screening purposes